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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,877	10/26/2000	David Balaban	3330.2	3718

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EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/697,877	Applicant(s) BALABAN, DAVID	
	Examiner Cynthia B Wilder	Art Unit 1637	<b>FILE</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 11-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i>        |

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**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to probe array, classified in class 536, subclass 24.3.
  - II. Claims 11-27, drawn to method for determining target sequence, classified in class 435, subclass 6.
  - III. Claims 28-35 and 45-49, drawn to computer software product, classified in class 345, subclass 530.
  - IV. Claims 36-44, drawn to method of designing a probe, classified in class 358, subclass 502.
2. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~ I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the probe array of Invention I can be used in a materially different process such as in fingerprinting procedures to classify cell types or diagnostic procedures to identify disease-specific conditions.
3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mode of operations and different effects. For example, the probe array of

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invention I are drawn to set of oligonucleotides immobilized on a substrate for use in hybridization methods for interrogating a joining sequence of a target molecule whereas the computer software product of Invention III is drawn to a computer code and computer readable media for receiving and storing information. The searches of the different Inventions of I and III are not coextensive in the art because probe arrays not necessary or required for the function of a computer software product.

4. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the probe array can be designed by a materially different process besides the ink-jet technology such as by the very large scale immobilized polymer synthesis (VLSIPS<sup>TM</sup>) technology.

5. Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the different inventions have different mode of operations. For example, Invention II is drawn to a method of determining a target sequence using a set of probes in an array via hybridization techniques whereas invention III is drawn to a computer software product comprising computer code and computer readable media for receiving and storing information or data and Invention IV is drawn to a method of designing probe array using ink-jet technology. The different are patentable distinct requiring different fields of search.

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6. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Mr. Wei Zhou on April 29, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 11-49 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102(b)***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cronin et al. (WO 98/30883, published July 16, 1998). Regarding claim 1, Cronin et al. teach a nucleic acid probe array comprising a set of probes for interrogating a joining sequence between a first sequence element and a second sequence element (page 6, lines 18-36).

Regarding claim 2, Cronin et al. teach wherein the nucleic acid are oligonucleotide (page 11, lines 16-17).

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Regarding claim 3, Cronin et al. teach wherein the sequence elements may be exons (page 11, lines 5-15 and lines 31-37 bridging top of page 12, lines 1-4).

Regarding claims 5 and 6, Cronin et al. teach wherein the joining (tiling) sequences are at least 20 (clm 5) or at least 30 bases (clm 6) (page 20, lines 18-22). Therefore, the claimed invention of claims 1-3, 5 and 6 are anticipated by the reference of Cronin et al.

***Claim Rejections - 35 USC § 102(e)***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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10. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Hacia et al. (US 6,342,355 B1, filed Jan. 5, 2000). Regarding claim 1 and 2, Hacia et al. teach a nucleic acid probe said nucleic acid is an oligonucleotide (col. 8. lines 3-21).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al. in view of Hacia et al. and further in view of Lockhart et al. (6,040,138, pd March 21, 2000). Regarding claims 4-10, Cronin et al. teach a nucleic acid probe array comprising a set of probes for

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interrogating a joining sequence between sequence elements wherein said nucleic acid are oligonucleotides and the sequence elements may be exons. In a method similar to Cronin et al., Hacia teach a nucleic acid probe array wherein the array comprise a set of probes for interrogating sequence elements wherein the elements may be genes or variation of a gene. Hacia et al. further teach wherein the array comprise joining sequences at a 3' end and a 5' end of a sequence element. (col. 8, lines 3-12). The reference further teaches wherein a sequence element may comprise a joining sequence having at least at least 10 to 1,000,000 bases (col. 8, lines 3-21) . Hacia et al. further teach wherein the probes of the probe set may vary from 1 to 100,000 (col. 8, lines 20-21). The nucleic acid array of Cronin et al. and Hacia et al. differs from the instant invention in that the references do not expressly teach wherein the probes are immobilized on a substrate at a density of at least 100 probes/cm<sup>2</sup>. However, the reference do suggest the use of a chip for the oligonucleotide array and teaches that the chip design provide redundant information which contributes to sensitivity and specificity (col. 13, lines 40-41). Lockhart et al teach a nucleic acid probe array comprising a set of probes for interrogating sequence elements. Lockhart teaches wherein the probes of the probe array are immobilized on a chip at a density greater than 100 probes/cm<sup>2</sup> (col. 3, lines 12-20). Lockhart teaches that such arrays are useful for large-scale analysis. Therefore, in view of the foregoing, one of ordinary skill in the art would have been motivated to provide a nucleic acid array as taught by Cronin et al. and Hacia et al. immobilized on a substrate at a density of 100 probes/cm<sup>2</sup> for the benefits of large scale analysis as taught by Lockhart et al. and for the advantage increase sensitivity and specificity as suggested by Hacia et al.



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***Conclusion***

13. No claims are allowed.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

April 30, 2002

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

4/30/02